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10/088,666	06/28/2002	Markus Fandke	216087	6893

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LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,666	FANDKE ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-63* is/are pending in the application.

4a) Of the above claim(s) *44,48 and 58-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,43,45-47 and 49-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 42-57, further electing SEQ ID NO: 1, 21, 73, and 74 in the reply filed on 9/13/04 is acknowledged. The traversal is on the ground(s) that the inventions defined by groups I and II are so linked to form a single general inventive concept, since the methods recited in the claims of group I require the nucleic acid sequences recited in the claims of group II. This is not found persuasive because the special technical feature to which applicant refers is (a) not required by all of the claims in group 1 (for example claim 42) and (b) is not a contribution over the prior art. For example, Patent Abstracts of Japan publication number 05015400, dated 26-01-93 teaches an oligonucleotide that consists of nucleotides 176-195 of instant SEQ ID NO: 1 (see nucleic acid II in the publication), which anticipates at least claims 58-60 of the instant application, and thus exemplifies that there is no special technical feature that is a contribution over the prior art.

2. Claims 44, 48, and 58-63 are withdrawn from prosecution as being drawn to non-elected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

3. All documents on the 1449 filed 20 March 2002 have been considered, including the search alignments. However, the search alignments have been lined through because they are not dated on the 1449 form. If applicant wishes for these to appear on the cover of any eventually issued US Patent, applicant should submit a new 1449 that provides the date the

search was run (or at least the date the print out was provided). The new 1449 will be signed off by the examiner as these alignments have been considered.

4. The file contains papers indicating that a 1449 and references were filed in an IDS on 6/28/02. The file contains the transmittal papers that would have accompanied the 1449 and references, but neither the 1449 nor the references have been entered into the file. It is not clear that references and the 1449 were received. Thus, no references have been considered in association with the IDS filed 6/28/02.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 42-43, 46-47, and 50-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to methods for detecting a microorganism relevant to brewing in a sample, and require the use of "a combination of at least two first nucleic acid molecules (primers), which hybridise with ***a region of a microbial nucleic acid conserved in microorganisms relevant to brewing*** (emphasis added)" and "a second nucleic acid molecule (probe), which specifically hybridizes with at least one amplification fragment that comprises a

sequence of the microbial nucleic acid ***specific for all microorganisms relevant to brewing or for one or several families, genera or species of microorganisms relevant to brewing***".

Dependent claims indicate that the primers and probes are selected from nucleic acids (i) "with" (broadly read as equivalent to comprising) a sequence according to SEQ ID NO: 1-107 or a fragment thereof at least 10 nucleotides long, (ii) a nucleic acid which specifically hybridizes with a nucleic acid according to (i); (iii) a nucleic acid which is at least 70% identical with a nucleic acid according to (i) or (ii), and a nucleic acid which is complementary to a nucleic acid according to (i) or (iii). For the claims which recite specific SEQ ID NO, instant SEQ ID NO: 1, 21, 73, and 74 are elected for prosecution herein.

Dependent claim 57 requires that the conserved region occurs in the "genome section" which contains the bacterial 23S and 5S genes. The term "genome section" is also quite broad, and encompasses the use of probes and primers that are not described such as those within the 23S and 5S gene, as well as surrounding regions of the genome.

The remaining rejected claims do not further define the sequences of the probes or primers.

The scope of the probes and primers utilized in the instantly claimed methods is enormous, for claims which do not recite specific SEQ ID NO includes the use of sequence from virtually anywhere within the genome of the recited organisms, provided it is a conserved region with respect to at least a single species or genera or family. The possible number of sequences encompassed within these claims is quite large. Indeed, even for the rejected claims which recite SEQ ID NO, the recitations within these claims are sufficiently broad so as to encompass nucleic

acid probes and primers to regions of the genome that are not disclosed in this application, and for which no written description of the many, many potential structures is provided.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only SEQ ID NO: 1, 21, 73 and 74 are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 42, 50, 53, 54, 55, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Satokari *et al.* (Internation Journal of Food Microbiology 45(1998) 119-127).

Satokari et al. teach detection of beer spoilage bacteria Megasphaera and Pectiunatus by PCR and subsequent detection of PCR amplicons by hybridization.

Thus, Satokari et al. teach a method for the detection of a microorganism relevant to brewing in a sample, which comprises the following steps:

(a) bringing the sample into contact with a combination of at least two first nucleic acid molecules (primers), which hybridize with a region of a microbial nucleic acid conserved in microorganisms relevant to brewing (p. 121, section 2.4) ;

(b) amplification of the microbial nucleic acid or a portion thereof to produce at least one amplification fragment (p. 121, section 2.4);

(c) bringing the amplification fragments obtained in step (b) into contact with at least one second nucleic acid molecule (probe), which specifically hybridizes with at least one amplification fragment that comprises a sequence of the microbial nucleic acid specific for all microorganisms relevant to brewing or for one or several families, genera, or species of microorganism relevant to brewing (p. 122, section 2.5); and

(d) detection of at least one hybrid nucleic acid which consists of an amplification fragment and a second nucleic acid molecule introduced in step (c) whereupon a microorganism relevant to brewing is detected in a sample (p. 122, section 2.5).

With regard to claim 50, Satokari et al. use PCR (p. 121, section 2.4).

With regard to claim 53, Satokari et al. teach that the second nucleic acid is modified to produce a detectable signal, the modification being a group (digoxigenin) which allows a indirect or direct reaction by means of an antibody conjugated to an enxyme (p. 122, section 2.5).

With regard to claims 54 and 55, Satokari et al. utilize first and second nucleic acids that are at least 15 nucleotides long (Table 2 and p. 122, section 2.5).

With regard to claim 57, Satokari et al. teach probes and primers that target 16S rDNA which is in the genome "section" which contains bacterial 23S and 5S genes. The 16S gene is considered to be within this section because it occurs next to the 23S gene in the bacterial

genome, and thus, relatively speaking, it is within this section. The specification does not define what it means to be within a genome "section" and thus this recitation is given its broadest reasonable interpretation.

Therefore, Satokari et al. anticipate the instantly rejected claims.

9. Claims 42, 43, 46, 47, 50, 53, 54, 55 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Nietupski *et al.* (5484909).

Nietupski *et al.* teach methods for the detection of beer spoilage microorganisms of the genera Lactobacillus and Pediococcus. Nietupski *et al.* teach an embodiment wherein a segemtn of a target organism gene encoding Lactobicillus rRNA is amplified in a polymerase chain reaction (see example 3, Col. 23) and then the amplicon is detected via a hybridization probe.

Thus, Nietupski et al. teach a method for the detection of a microorganism relevant to brewing in a sample, which comprises the following steps:

(a) bringing the sample into contact with a combination of at least two first nucleic acid molecules (primers), which hybridize with a region of a microbial nucleic acid conserved in microorganisms relevant to brewing (a step which is inherent to PCR) ;

(b) amplification of the microbial nucleic acid or a portion thereof to produce at least one amplification fragment;

(c) bringing the amplification fragments obtained in step (b) into contact with at least one second nucleic acid molecule (probe), which specifically hybridizes with at least one amplification fragment that comprises a sequence of the microbial nucleic acid specific for all microorganisms relevant to brewing or for one or several families, genera, or species of microorganism relevant to brewing; and

(d) detection of at least one hybrid nucleic acid which consists of an amplification fragment and a second nucleic acid molecule introduced in step (c) whereupon a microorganism relevant to brewing is detected in a sample.

With regard to claim 43, this claim broadly requires that the second nucleic acid (probe) be a nucleic acid with (interpreted as comprising) a fragment of SEQ ID NO: 1 that is 10 nucleotides long, or comprises a nucleic acid which is 70% identical to a fragment of SEQ ID NO: 1 that is 10 nucleotides long. Thus, the claim encompasses any method which utilizes a probe that comprises at least 7 nucleotides in common with SEQ ID NO: 1. Nietupski *et al.* teach a number of such probes for use in their methods, for example, SEQ ID NO: 9 taught by Nietupski *et al.* comprises nucleotides 12-19 of that sequence which are identical to nucleotides 202-209 of SEQ ID NO: 1. The instant claim language is quite broad in nature and encompasses the use of the probe taught by Nietupski *et al.*

With regard to claim 46, this claim broadly requires that the first nucleic acid molecules be nucleic acids with (interpreted as comprising) a fragment of SEQ ID NO: 1 that is 10 nucleotides long, or comprises a nucleic acid which is 70% identical to a fragment of SEQ ID NO: 1 that is 10 nucleotides long. Thus, the claim encompasses any method which utilizes a probe that comprises at least 7 nucleotides in common with SEQ ID NO: 1. Nietupski *et al.* teach a number of such probes for use in their methods, for example, SEQ ID NO: 9 taught by Nietupski *et al.* comprises nucleotides 12-19 of that sequence which are identical to nucleotides 202-209 of SEQ ID NO: 1. Likewise, SEQ ID NO: 10 taught by Nietupski *et al.* comprises nucleotides 14-21 of that sequence which are identical to the complement of nucleotides 194-201

of instant SEQ ID NO: 1. The instant claim language is quite broad in nature and encompasses the use of these probes taught by Nietupski *et al.* as the first and second nucleic acids.

With regard to claim 47, the claim does not require that the probe have a different sequence from one or both of the primers, and thus, since Nietupski *et al.* teach amplification and detection using this pair of probes as primers and then sandwich detection using the same (see Col. 24, SEQ ID NO: 9 is probe 2891 and SEQ ID NO: 10 is probe 2892), thus the teachings of Nietupski *et al.* anticipate this claim.

With regard to claim 50, Nietupski *et al.* teach amplification with PCR.

With regard to claim 53, Nietupski *et al.* teach detection with probes that are modified to produce a detectable signal, the modification being a radioactive group (Col. 8, line 55).

With regard to claim 54 and 55, the nucleic acids taught by Nietupski *et al.* are at least 15 nucleotides long.

With regard to claim 57, Nietupski *et al.* teach probes to the 23S gene region (Col. 7, lines 57-62, for example).

Thus, the teachings of Nietupski *et al.* anticipate the rejected claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Satokari *et al.* in view of Backman *et al.* (US 5792607).

Satokari et al. teach detection of beer spoilage bacteria Megasphaera and Pectiunatus by PCR and subsequent detection of PCR amplicons by hybridization.

Thus, Satokari et al. teach a method for the detection of a microorganism relevant to brewing in a sample, which comprises the following steps:

(a) bringing the sample into contact with a combination of at least two first nucleic acid molecules (primers), which hybridize with a region of a microbial nucleic acid conserved in microorganisms relevant to brewing (p. 121, section 2.4) ;

(b) amplification of the microbial nucleic acid or a portion thereof to produce at least one amplification fragment (p. 121, section 2.4);

(c) bringing the amplification fragments obtained in step (b) into contact with at least one second nucleic acid molecule (probe), which specifically hybridizes with at least one amplification fragment that comprises a sequence of the microbial nucleic acid specific for all microorganisms

relevant to brewing or for one or several families, genera, or species of microorganism relevant to brewing (p. 122, section 2.5); and

(d) detection of at least one hybrid nucleic acid which consists of an amplification fragment and a second nucleic acid molecule introduced in step (c) whereupon a microorganism relevant to brewing is detected in a sample (p. 122, section 2.5).

Satokari *et al.* does not teach a method which utilizes a ligase chain reaction. However, at the time the invention was made, a variety of amplification techniques were known, one of which was the ligase chain reaction. Backman *et al.* teach improved methods of ligase chain reaction for amplification of nucleic acid templates.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have utilized the ligase chain reaction for the detection of microorganisms as taught by Satokari *et al.* One would have been motivated to have modified the methods taught by Satokari *et al.* in order to provide an alternative method for the amplification of the target molecules.

13. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Satokari *et al.* in view of Fraiser *et al.* (US 5744311).

Satokari et al. teach detection of beer spoilage bacteria Megasphaera and Pectiunatus by PCR and subsequent detection of PCR amplicons by hybridization.

Thus, Satokari et al. teach a method for the detection of a microorganism relevant to brewing in a sample, which comprises the following steps:

(a) bringing the sample into contact with a combination of at least two first nucleic acid molecules (primers), which hybridize with a region of a microbial nucleic acid conserved in microorganisms relevant to brewing (p. 121, section 2.4) ;

(b) amplification of the microbial nucleic acid or a portion thereof to produce at least one amplification fragment (p. 121, section 2.4);

(c) bringing the amplification fragments obtained in step (b) into contact with at least one second nucleic acid molecule (probe), which specifically hybridizes with at least one amplification fragment that comprises a sequence of the microbial nucleic acid specific for all microorganisms relevant to brewing or for one or several families, genera, or species of microorganism relevant to brewing (p. 122, section 2.5); and

(d) detection of at least one hybrid nucleic acid which consists of an amplification fragment and a second nucleic acid molecule introduced in step (c) whereupon a microorganism relevant to brewing is detected in a sample (p. 122, section 2.5).

Satokari *et al.* does not teach a method which utilizes an isothermal. However, at the time the invention was made, a variety of amplification techniques were known, one of which was the ligase chain reaction. Fraiser *et al.* teach an isothermal stand displacement amplification reaction.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have utilized the isothermal stand displacement amplification reaction for the detection of microorganisms as taught by Satokari *et al.* One would have been motivated to have modified the methods taught by Satokari *et al.* in order to provide an alternative method for the amplification of the target molecules, and to take advantage of the SDA taught by Fraiser *et*

al., which Fraiser *et al.* teach has improved specificity, efficiency, reduced background amplification, and potenetially improved yields (Abstract and throughout).

14. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Satokari *et al.* in view of Fugono *et al.* (US 5738993).

Satokari et al. teach detection of beer spoilage bacteria Megasphaera and Pectiunatus by PCR and subsequent detection of PCR amplicons by hybridization.

Thus, Satokari et al. teach a method for the detection of a microorganism relevant to brewing in a sample, which comprises the following steps:

(a) bringing the sample into contact with a combination of at least two first nucleic acid molecules (primers), which hybridize with a region of a microbial nucleic acid conserved in microorganisms relevant to brewing (p. 121, section 2.4) ;

(b) amplification of the microbial nucleic acid or a portion thereof to produce at least one amplification fragment (p. 121, section 2.4);

(c) bringing the amplification fragments obtained in step (b) into contact with at least one second nucleic acid molecule (probe), which specifically hybridizes with at least one amplification fragment that comprises a sequence of the microbial nucleic acid specific for all microorganisms relevant to brewing or for one or several families, genera, or species of microorganism relevant to brewing (p. 122, section 2.5); and

(d) detection of at least one hybrid nucleic acid which consists of an amplification fragment and a second nucleic acid molecule introduced in step (c) whereupon a microorganism relevant to brewing is detected in a sample (p. 122, section 2.5).

Satokari *et al.* do not teach a method which oligonucleotides that are modified in that up to 20% of the nucleotides in 10 consecutive nucleotides are replaced by nucleotides that do no naturally occur in bacteria. However, at the time the invention was made, it was routine to use modified nucleotides in oligonucleotide primers and probes. For example, Fugono *et al.* teach amplification primers which have the base inosine incorporated within the primer. Fugono *et al.* teach methods which utilize primers wherein at least one base is replaced with inosine, and teach that the use of these alternative bases results in increased specificity (Col. 3).

Therefore, It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the methods taught by Satokari *et al.* so as to have used modified bases as taught by Fugono *et al.* in order to have achieved the benefits of using such modified bases as taught by Fugono *et al.*

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43, 45, 46, 47, and 49 are indefinite because each of these recites nucleic acids "with a sequence according to one of SEQ ID NO:..." and it is not clear if this language is intended to be open or closed claim language with regard to the SEQ ID NO's. That is, it is not clear if the claims are intended to require nucleic acids comprising or consisting of the SEQ ID NO or fragments thereof, as appropriate. For interpretation with regard to the prior art, the

claims herein have been construed so as to consider this language to be open claim language equivalent in scope to comprising. Clarification is requested.

Conclusion

17. Nucleic acids comprising instant SEQ ID NO: 1, 21, 73, and 74, each in their entirety are free of the prior art. Thus, methods which require any one of these are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

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Juliet C. Switzer
Examiner
Art Unit 1634

November 29, 2004